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10/584,867	06/29/2006	Michael Schneider	0262-061920	7715

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EXAMINER	
TOUSSAINT, DALILA	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,867	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	DALILA TOUSSAINT	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23-30* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to the reply filed on March 24, 2009. Claims 21 and 23-30 are pending and claims 22 stands withdrawn.

Claim Rejections - 35 USC § 112

1. The 112 second paragraph rejection is hereby withdrawn in view of applicant's amendment.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 21 and 23-30 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sawatzki et al. WIPO publication WO 9933355**.

a. Referring to claims 21, and 23-29, Sawatzki et al. discloses a fat blend made of lecithin-based fat, see abstract shown below. The oil (fat) contains phospholibids (often also described as lecithins) and the lecithin contains triglycerides (page 4, ¶ 5, line 6-11).

The lecithin based fat comes from egg yolk and/or other fish, and marine mammals (page 4, ¶ 5, line 2-7).

> The invention relates to an oil, fat and/or lecithin-based fat blend containing polyunsaturated fatty acids. The inventive fat blend is characterized in that the fatty acids gamma-linolenic, stearidonic acid and eicosapentaenoic together make up 10 to 500

> mg/g total fatty acids. The gamma-linolenic and eicosapentaenoic acids each represent 20 to 50 wt. % and the stearidonic acid represents 15 to 50 wt. % of the sum of these three fatty acids. The inventive fat blend can be incorporated into a dietetic or a pharmaceutical product, especially a dietetic food, and can be used especially for administering to patients suffering from chronic/inflammatory diseases, disorders of the lipid metabolism, a weakened immune function and/or a restricted lipolytic capacity of the gastrointestinal tract.

Also, Sawatzki et al. disclose producing the fat blend by chromatographic separation of animal fats and oils to obtain polyunsaturated fatty acid that have long carbon chains of desaturated fatty acids (C20 and C22; page 1, ¶ 4, line 1-5) on page 4, ¶ 4, line 6-11.

> In addition, for example GLA- and SA-rich concentrates produced in chemical or enzymatic ways and also those obtained from the said sources by chromatographic separation can be used. As animal fats and oils, for example, egg oils, fish oils and oils from marine mammals, and also for example eicosapentaenoic acid-rich or stearidonic acid-rich concentrates produced in chemical or enzymatic ways and also those obtained from these raw materials by chromatographic separation can be used.

The fat blend according to the reference embodiment can be in any desired nature i.e. a fat emulsion, a liquid food, a reconstituted powder food or a reconstitutable powder food (page 5, ¶ 4, line 1-7). Also, "the dietetic foodstuffs according to the invention contain not only a fat mixture or a fat blend of the type

described above, but can also contain other products, for example protein of animal and/or plant origin, e.g. milk, whey, peas, wheat and/or soya, in the form of complex and/or hydrolysed protein with or without addition of free amino acids and/or dipeptides as well as carbohydrates (maltodextrins), vitamins, roughage, minerals, trace elements, choline, taurine, carnitine, inositol and nucleotides in different quantity proportions and optionally water. These further components can be mixed with the fat blend as desired."(page 6, ¶ 6, line 1-7)

Note that the reference specification discloses (see above) that the fat blend can have any desired amount of carbohydrates; therefore the remaining limitations are inherent.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Levin US patent 3881034** in view of **Sawatzki et al. WIPO publication WO 9933355** and evidenced by **Hsieh et al. US patent 5302405**.

b. Referring to claim 30, Levin discloses a stable dried egg powder containing a reduced amount of cholesterol (fat), made by removing the water and fat from whole raw eggs and then adding antioxidants or other additives into the mixture (abstract). The egg fat that has been removed by an extraction process is partly replaced by the addition of egg fat (animal fat) to make a low cholesterol egg with good flavor. It has been found that replacement of 15% to 50% of the original fat of the egg, gives a highly satisfactory balance of low cholesterol and good flavor (column 2, line 7-14). Also, the removed egg oil is replaced with oil such as butter, corn, coconut, soybean, cottonseed, flavors such as maple, fruit with or without fat, and antioxidant (column 2, line 35-50 and example 4). Though Levin discloses removing fat from the egg content to make a "fat-free" product having less than 5 wt.% free fat, Levin discloses maintaining the bound fat in the product but being substantially free of fat (cholesterol) (column 1, line 58-60). As evidenced by Hseih, "bound" fat are egg components such as phospholipids and lipoprotein complexes (Hseih; column 3, line 28-30). Thus, solely for example egg oil is replaced with oils such as butter, corn, coconut, soybean, cottonseed, flavors such as maple, fruit with or without fat, egg fat, and antioxidant (column 2, line 35-50 and example 4). This disclosure

clearly suggests to one skilled in the art that the fat removed is of egg fat, in particular egg oil.

However, Levin is silent to long-chain polyunsaturated fatty acids having at least 20 carbon atoms present in the fat or oil component in an amount of more than 5 wt.% of the total fatty acid content and Levin is silent to the carbohydrate content of the solid fat product.

Sawatzki discloses a fat blend using egg fat such as lecithin's derived from egg-yolk as a result of modified feeding, displaying w3-PUFA (polyunsaturated fatty acids) that has long chains (C20 and C22) and higher desaturated fatty acids (Sawatzki; page 1, ¶ 4, line 1-5 and 4, ¶ 4-5) and other natural w3-PUFA-containing lecithin, such as fish oil. The oil (fat) contains phospholipids (often also described as lecithins) and the lecithin contains triglycerides (page 4, ¶ 5, line 6-11). The fat blend is characterized in that the fatty acids gamma-linolenic, stearidonic acid and eicosapentaenoic together make up 10 to 500 mg/g total fatty acids. Furthermore, the fat blend further consist of other products, for example protein of animal and/or plant origin, e.g. milk, whey, peas, wheat and/or soya, in the form of complex and/or hydrolyzed protein with or without addition of free amino acids and/or dipeptides as well as carbohydrates (maltodextrins), vitamins, roughage, minerals, trace elements, choline, taurine, carnitine, inositol and nucleotides in different quantity proportions and optionally water. These additional product components can be mixed with the fat blend as desired."(Sawatzki; page 6, ¶ 6, line 1-7)

Note that the reference specification discloses (see above) that the fat blend can have any desired amount of additional products of carbohydrates and proteins of animal and or plant origin. It is expected that additional product such as animal product derived from egg product would be used. The fat blend according to the reference embodiment can be in any desired nature i.e. a fat emulsion, a liquid food, a reconstituted powder food or a reconstitutable powder food (Sawatzki; page 5, ¶ 4, line 1-7).

Regarding the fats of Levin, it would have been obvious to one having ordinary skill in the art at the time of invention to include the egg fats and other products as Sawatzki to improve the flavor of the fat mixture and to also enhance the of fatty acid metabolism such as eicosanoid metabolism in patients with various diseases (Sawatzki; page 2, ¶ 3).

Response to Arguments

7. Applicant's arguments filed March 24, 2009 have been fully considered but they are not persuasive. New rejections are in light of applicant's amendment to limitation of claim 30.

Applicant argues Sawatzki fails to teach how to increase the oxidation stability and bio-availability of bioactive LC-PUFAs with at least 20 carbon atoms and that Sawatzki discloses neither a solid fat product based on whole egg or egg yolk, nor a product having a content of more than 5 wt% of LC-PUFAs with at least 20 carbon atoms based on the total fatty acid content.

In response to argument, Sawatzki discloses a fat blend using egg fat such as lecithin's derived from egg-yolk as a result of modified feeding, displaying w3-PUFA (polyunsaturated fatty acids) that has long chains (C20 and C22) and higher desaturated fatty acids (Sawatzki; page 1, ¶ 4, line 1-5 and 4, ¶ 4-5) and other natural w3-PUFA-containing lecithin, such as fish oil. The lecithin content is present up to 40 wt.% of the total lipid (Sawatzki; page 4, ¶ 2). The fat blend is characterized in that the fatty acids gamma-linolenic, stearidonic acid and eicosapentaenoic together make up 10 to 500 mg/g total fatty acids. Furthermore, the fat blend further consist of other products, for example protein of animal and/or plant origin, e.g. milk, whey, peas, wheat and/or soya, in the form of complex and/or hydrolyzed protein with or without addition of free amino acids and/or dipeptides as well as carbohydrates (maltodextrins), vitamins, roughage, minerals, trace elements, choline, taurine, carnitine, inositol and nucleotides in different quantity proportions and optionally water. These additional product components can be mixed with the fat blend as desired.(Sawatzki; page 6, ¶ 6, line 1-7).

Note that the reference specification discloses (see above) that the fat blend can have any desired amount of additional products of carbohydrates and proteins of animal and or plant origin. It is expected that an animal product derived from egg product would be used. Moreover as disclosed above in the rejection the lecithin based fat comes from egg yolk and/or other fish, and marine mammals (page 4, ¶ 5, line 2-7). Therefore it is inherent that within the base ingredient there is egg yolk with w3-PUFA with the amount recited by the limitation in claim 21. Also the claim limitation doesn't recite the use of

"bioactive" LC-PUFA. However, it is disclosed by Sawatzki, to stabilize high-unsaturated fat mixture before autooxidative decay with known natural and synthetic antioxidants. Furthermore, the initial contents of lecithins from animal, plant and/or microbial (bioactive) origin in the fat mixture to contribute to the oxidation stability (Sawatzki; page 4, ¶ 6- page 5, ¶ 7).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DALILA TOUSSAINT whose telephone number is

(571)270-7088. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DT

/KEITH D. HENDRICKS/
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